

# EXHIBIT 5

**PRE-TRIAL ORDER  
EXHIBIT 5  
ISSUES OF LAW THAT REMAIN TO BE LITIGATED**

Nippon Shinyaku and NS Pharma identify the below listed issues of law for trial. To the extent that any issues of fact set forth in **Exhibit 3** of the Joint Pretrial Order may be considered issues of law, Nippon Shinyaku and NS Pharma incorporate those portions of **Exhibit 3** by reference. Should the Court determine that any issue identified in this Exhibit as an issue of law is appropriately considered an issue of fact, Nippon Shinyaku and NS Pharma incorporate such issues by reference into its statement of issues of contested facts set forth in **Exhibit 3**.

Nippon Shinyaku and NS Pharma's identification of issues of law that remain to be litigated is based, in part, on Nippon Shinyaku and NS Pharma's understanding of Sarepta and/or UWA's arguments regarding no willfulness, invalidity, and damages, which are based on Sarepta and/or UWA's interrogatory responses, contentions, expert reports, and summary judgment briefing. Nippon Shinyaku and NS Pharma reserve the right to amend this statement in light of Sarepta's and/or UWA's statement of fact or law that remain to be litigated or any revisions thereto. Nippon Shinyaku and NS Pharma reserve the right to address additional issues not set forth herein to the extent they are raised by Sarepta and/or UWA at trial. These issues of law may change based on the Court's decision on various motions, including *Daubert* motions and motions *in limine*. Nippon Shinyaku and NS Pharma provide the instant statement of issues of law that remain to be litigated based on representations Sarepta has made in the Pretrial Order cover pleading, including Sarepta's stipulation of infringement.

## **I. INFRINGEMENT<sup>1</sup>**

### **A. Issues to Be Litigated**

1. Whether Nippon Shinyaku proved by a preponderance of the evidence that Sarepta's infringement of the NS Patents was willful.

### **B. Legal Authority**

#### **i. Willful Infringement**

"The concept of 'willfulness' requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323 (Fed. Cir. 2021) (quoting *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020)); *see also Wrinkl, Inc. v. Facebook, Inc.*, No. 20-CV-1345-RGA, 2021 WL 4477022, at \*2 (D. Del. Sept. 30, 2021) (citing *SRI Int'l* for the same). This standard may be satisfied by a finding of "subjective willfulness" based on the defendant having acted in the face of a risk of infringement that was "either known or so obvious that it should have been known to the accused infringer." *WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1362 (Fed. Cir. 2016) (quoting *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 136 S.Ct. 1923, 1930 (2016)), *rev'd on other grounds*, 138 S. Ct. 2129 (2018); *Wrinkl*, 2021 WL 4477022, at \*2 (stating the same).

## **II. INVALIDITY**

### **A. Issues to Be Litigated**

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<sup>1</sup> In light of Sarepta's stipulation of infringement, NS is relieved of any burden to demonstrate infringement.

2. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the Asserted UWA Patent Claims are invalid for failing to satisfy the written description requirement under 35 U.S.C. § 112, ¶ 1.

3. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the Asserted UWA Patent Claims are invalid for failing to satisfy the enablement requirement under 35 U.S.C. § 112, ¶ 1.

**B. Legal Authority**

**i. Level of Ordinary Skill in the Art**

Each of written description and enablement are viewed from or take into account the perspective of one of ordinary skill in the art. *See, e.g., Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 982 (Fed. Cir. 2021) (explaining that “whether a patent is enabled—or requires undue experimentation—are questions that must be viewed ‘from the perspective of one of ordinary skill in the art’” (citation omitted)); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (explaining that “the test for sufficiency” of a patent’s written description “is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date”); *Sonos, Inc. v. D & M Holdings Inc.*, 297 F. Supp. 3d 501, 513 (D. Del. 2017) (Bryson, J., sitting by designation) (“Enablement and indefiniteness are both assessed in light of the perspective of a person of ordinary skill in the art.”).

“Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citation omitted).

## **ii. Obviousness**

A patent claim is invalid as obvious under 35 U.S.C. § 103 “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103 (2006); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007).

Obviousness is a question of law with underlying factual inquiries, including: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) any relevant objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). “Obviousness requires, *inter alia*, a finding that a skilled artisan would have been motivated to combine the teachings of prior art in such a way that the combination discloses the claimed limitations. The inquiry into the existence of a motivation to combine assumes that a skilled artisan is a person of ordinary creativity with common sense, common wisdom, and common knowledge. Thus, an obviousness determination does not always require prior art to expressly state a motivation for every obvious combination. Nor does an obviousness showing ‘require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.’” *Elektta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1374 (Fed. Cir. 2023) (internal citations omitted).

## **iii. Secondary Considerations of Non-Obviousness**

A patent may not be invalidated for obviousness without consideration of the “objective considerations” of nonobviousness, including the commercial success of the patented invention,

satisfaction of a long-felt unmet need, copying, skepticism, unexpected results, and failure of others to achieve the patented invention. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1076-78 (Fed. Cir. 2012) (citing *Graham*, 383 U.S. at 17-18); *see also InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1347 (Fed. Cir. 2014). “In order to accord substantial weight to secondary considerations in an obviousness analysis, ‘the evidence of secondary considerations must have a ‘nexus’ to the claims, i.e., there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.’” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

#### **vii. Written Description**

A patentee is required to provide a disclosure sufficient to convey with reasonable clarity to persons skilled in the art, as of the effective filing date, that the patentee in fact invented what is claimed. *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2014). That is, the patent specification, including its figures and claims, must allow a person of ordinary skill to easily recognize that the patentee was in possession of the claimed invention as of his/her asserted priority date. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). Compliance with the written description requirement involves both an assessment of the scope of the claims and the adequacy of the specification to support claims of such scope. *See id.* The test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. *Id.* A description that merely renders the invention obvious does not satisfy the requirement. *Id.*

“[T]he hallmark of written description is disclosure.” *Id.* “When a patent claims a genus using functional language to define a desired result, ‘the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result.’” *AbbVie Deutschland*

*GmbH & Co., KG v. Janseen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014) (quoting *Ariad*, 598 F.3d at 1349). “[W]ritten description of a broad genus requires description not only of the outer limits of the genus but also of either a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus.” *Regents of Univ. of Minnesota v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023) (citing *Ariad*, 598 F.3d at 1350-52). “In the absence of that guidance [into what compounds beyond the examples and formulas, if any, would provide the same result], the listed examples and formulas cannot provide adequate written description support for undisclosed [species].” *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019).

To demonstrate possession of a genus through “a representative number of species falling within the scope of the genus,” the specification must “describ[e] a variety of materials constituting the genus.” *Ariad*, 598 F.3d at 1350. “[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute.” *Id.* As the Federal Circuit has explained, “relatively few representative examples” do not suffice where, as here, “tens or hundreds of thousands of possible” structural candidates exist, and yet “the [accused product] is conspicuously absent.” *Idenix*, 941 F.3d at 1165.

#### **viii. Enablement**

A patent’s specification must “enable any person skilled in the art . . . to make and use” the patented invention without “undue experimentation.” 35 U.S.C. § 112(a); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Under this standard, “[t]hat some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive.” *Atlas*

*Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). For example, “[e]nablement is not precluded by the necessity for some experimentation such as routine screening,” *Wands*, 858 F.2d at 736-37, but rather by whether the “experimentation needed to practice the invention” is “undue experimentation,” *id.* at 737. “In addition, extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques.” *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013) (citing *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998)). As such, “[t]he key word” for the enablement inquiry “is ‘undue,’ not ‘experimentation.’” *Wands*, 858 F.2d at 737/

“Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” *Id.* Those considerations, known as the “*Wands* factors,” include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* (citation omitted).

The burden of proof is on the patent challenger to show lack of enablement by clear and convincing evidence. *See Cephalon*, 707 F.3d at 1336, 1337.

### **III. ix. UNENFORCEABILITY<sup>2</sup>**

#### **A. Issues to Be Litigated**

4. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the Asserted UWA Patent Claims are unenforceable due to inequitable conduct.

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<sup>2</sup> Inequitable conduct will be tried during the bench trial portion of this case.



## **B. Legal Authority**

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc). “To prove inequitable conduct, the challenger must show by clear and convincing evidence that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive the PTO.” *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012) (citing *Therasense*, 649 F.3d at 1287).

“A party alleging inequitable conduct, however, need not strictly demonstrate but-for materiality in all cases.” *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013). For example, “[w]here the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit,” materiality is presumed. *Id.* (quoting *Therasense*, 649 F.3d at 1292); *see also Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014); *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012).

“Specific intent to commit acts constituting inequitable conduct may be inferred from indirect and circumstantial evidence.” *Ohio Willow*, 813 F.3d at 1358. Further, because “direct proof of intent to mislead is normally absent,” the Federal Circuit holds that submitting a false affidavit during prosecution “will support the conclusion that the affidavit in which they were contained was the chosen instrument of an intentional scheme to deceive the PTO.” *Rohm Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983). Deceptive intent has been found where assertions made in the specification were misleadingly incomplete or inaccurate. *Apotex*, 763 F.3d at 1362. “An inference of an intent to deceive is appropriate where the applicant

engages in a pattern of lack of candor, including whether the applicant repeatedly makes factual representations contrary to the true information he had in his possession.” *Regeneron Pharms. Inc. v. Merus N.V.*, 864 F.3d 1343,1351 (Fed. Cir. 2017) (quoting *Apotex*, 763 F.3d at 1362).

#### **IV. DAMAGES**

##### **A. Issues**

5. Whether and what amount of damages Nippon Shinyaku is entitled to for Sarepta’s infringement of the NS Patents, including whether and in what amount Nippon Shinyaku is entitled to enhanced damages for willful infringement.

6. Whether Nippon Shinyaku is entitled to an award of prejudgment and post-judgment interest and, if so, the dollar amount of such award.

7. Whether Nippon Shinyaku and/or NS Pharma are entitled to a finding that this case is exceptional pursuant to 35 U.S.C. § 285.

8. Whether Nippon Shinyaku and/or NS Pharma are entitled to costs and, if so, the dollar amount of such costs.

9. Whether Nippon Shinyaku is entitled to post-judgment relief in the form of an ongoing royalty for Sarepta’s manufacture, use, import, sale, or offer for sale of VYONDYS 53<sup>®</sup> until after the expiration of the NS Patents.

##### **B. Legal Authority**

###### **(i) Patent Damages Generally**

Upon a finding of infringement, the patentee shall be awarded “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” 35 U.S.C. § 284.

A patent holder who does not hold exclusive rights to a patent “has no entitlement under the patent statutes to itself collect...damages for any losses it incurred due to infringement.” *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004). In other words, “[a] nonexclusive license confers no constitutional standing...because a nonexclusive licensee suffers no legal injury from infringement.” *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005); *see also WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010) (a non-exclusive or “bare” licensee “suffers no legal injury from infringement”).

### **(ii) Patent Damages - Lost Profits**

To recover lost profits damages for patent infringement, the patent owner must show a reasonable probability that it would have received the additional profits but for the infringement. *King Instruments Corp. v. Perego*, 65 F.3d 941, 952 (Fed. Cir. 1995); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). “There is no particular required method to prove but for causation” in patent cases. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017). “One useful, but non-exclusive method to establish the patentee's entitlement to lost profits is the . . . test first articulated by the Sixth Circuit” in *Panduit Corp. v. Stahl Brothers Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). *Mentor Graphics*, 851 F.3d at 1284 (internal quotation marks and citation omitted). The *Panduit* test requires the patentee to show: (1) “demand for the patented product”; (2) “absence of acceptable noninfringing substitutes”; (3) “manufacturing and marketing capability to exploit the demand”; and (4) “the amount of profit that ... would have [been] made.” 575 F.2d at 1156.

### **(iii) Patent Damages – Reasonable Royalty**

The reasonable royalty may be based on the “supposed result of hypothetical negotiations between the plaintiff and defendant.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1357 (Fed. Cir. 2012). “While the Federal Circuit has not

prescribed a specific methodology for calculating a reasonable royalty, courts rely upon the fifteen factors set forth in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).” *St. Clair Intellectual Prop. Consultants, Inc. v. Canon, Inc.*, No. 03-241, 2004 WL 2213562 (D. Del. Sept. 28, 2004). “[I]n conducting the hypothetical negotiation, the Court is permitted to look to events and facts that occurred after the infringement began.” *Mobil Oil Corp. v. Amoco Chems. Corp.*, 915 F. Supp. 1333, 1353 (D. Del. 1994).

#### **(iv) Pre- and Post-Judgment Interest**

Title 35 provides for the calculation of damages “together with interest . . . as fixed by the court.” 35 U.S.C. § 284. “Unless a federal statute, these rules, or a court order provides otherwise, costs—other than attorney’s fees—should be allowed to the prevailing party.” Fed. R. Civ. P. 54. “[P]rejudgment interest shall ordinarily be awarded absent some justification for withholding such an award.” *Nickson Indus., Inc. v. Rol Mfg. Co., Ltd.*, 847 F.2d 795, 800 (Fed. Cir. 1988) (citation omitted). “[P]rejudgment interest should be awarded from the date of infringement to the date of judgment.” *Id.* (citation omitted).

“[I]nterest shall be allowed on any money judgment in a civil case recovered in a district court.” 28 U.S.C. § 1961(a). “Post-judgment interest is awarded on monetary judgments recovered in all civil cases,” including ones for patent infringement. *Transmatic, Inc. v. Gulton Indus., Inc.*, 180 F.3d 1343, 1347 (Fed. Cir. 1999). Post-judgment interest is governed by regional circuit law. *Id.* at 1348. Interest begins to accrue on the date of the entry of judgment. *Loughman v. Consol-Pa. Coal Co.*, 6 F.3d 88, 97 (3d Cir. 1993). Courts in this district routinely award post-judgment interest in patent infringement cases. *See, e.g., nCUBE Corp. v. SeaChange Int’l, Inc.*, 313 F. Supp. 2d 361, 392 (D. Del. 2004) (awarding post-judgment interest to patentee for defendant’s willful infringement); *TruePosition Inc. v. Andrew Corp.*, 611 F. Supp. 2d 400, 414 (D. Del. 2009) (awarding post-judgment interest for patent infringement).

**(v) Exceptionality, Enhanced Damages, and Attorneys' Fees**

District courts have discretion to “increase the damages up to three times the amount found or assessed.” 35 U.S.C. § 284. In determining whether to enhance damages based on willfulness, a court considers “the factors set forth in *Read Corporation v. Portec Inc.*, 970 F.2d 816, 826–27 (Fed. Cir. 1992), *overruled on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).” *Green Mountain Glass LLC v. Saint-Gobain Containers, Inc.*, 300 F. Supp. 3d 610, 628 (D. Del. 2018). Those factors are “(1) deliberate copying; (2) defendant’s investigation and good faith-belief of invalidity or non-infringement; (3) litigation behavior; (4) defendant’s size and financial condition; (5) closeness of the case; (6) duration of the misconduct; (7) remedial action by the defendant; (8) defendant’s motivation for harm; and (9) attempted concealment of the misconduct.” *Id.* (citing *Read*, 970 F.2d at 826-27).

“The court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285. To be a “prevailing party,” a party “must win a dispute within the case in favor of it that materially alters the legal relationship between the parties at the time of the judgment.” *Parallel Iron LLC v. NetApp Inc.*, 2014 WL 4540209, at \*3 (D. Del. Sept. 12, 2014). “An exceptional case ‘stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.’” *Intellectual Ventures I LLC v. Trend Micro Inc.*, 944 F.3d 1380, 1383 (Fed. Cir. 2019) (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014)). “District courts may determine whether a case is ‘exceptional’ in the case-by-case exercise of their discretion, considering the totality of the circumstances.” *Id.*

**(vi) Costs**

Under Federal Rule of Civil Procedure 54(d), costs should be allowed to the prevailing party. Under 28 U.S.C. § 1920, the prevailing party may recover the following costs: (1) fees of the clerk and marshal; (2) fees for printed or electronically recorded transcripts necessarily obtained for use in this case; (3) fees and disbursements for printing and witnesses; (4) fees for exemplification and the costs of making copies of any materials where the copies are necessarily obtained for use in the case; (5) docket fees under 28 U.S.C. § 1923; and (6) compensation of court appointed experts, compensation of interpreters, and salaries, fees, expenses, and costs of special interpretation services under 28 U.S.C. § 1828. *See also* D. Del. Civ. L.R. 54.1.

**(vii) Ongoing Relief**

“There are several types of relief for ongoing infringement that a court can consider,” including “an injunction” and “an ongoing royalty.” *Whitserve LLC v. Computer Packages, Inc.*, 694 F.3d 10 (Fed. Cir. 2012). If a court does not award an injunction against ongoing infringement, then “absent egregious circumstances . . . the patentee remains entitled to an ongoing royalty.” *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 807 F.3d 1311, 1332-33 (Fed. Cir. 2015). When awarding an ongoing royalty, “post-verdict factors should drive the ongoing royalty rate,” including the patent holder’s “improved bargaining position” resulting from the judgment of liability. *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1297-98 (Fed. Cir. 2018).

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